

## WHAT IS CLAIMED IS:

1                   1. A method for use in the diagnosis of endometriosis in a subject  
2 comprising the steps of:

3                   detecting a test amount of a prothymosin gene product in a  
4 sample from the subject; and

5                   comparing the test amount with a normal amount of the  
6 prothymosin gene product in a control sample,

7                   whereby a test amount above the normal amount provides a  
8 positive indication in the diagnosis of endometriosis.

1                   2. The method of claim 1 wherein the sample comprises ectopic  
2 endometrial tissue, eutopic endometrial tissue, peritoneal fluid, blood, vaginal  
3 secretion or urine.

1                   3. The method of claim 1 wherein the prothymosin gene product is  
2 prothymosin mRNA or cDNA.

1                   4. The method of claim 3 wherein the step of detecting comprises  
2 the steps of:

3                   contacting the prothymosin mRNA or cDNA with a  
4 polynucleotide of at least 7 to about 50 nucleotides in length that specifically  
5 hybridizes to the prothymosin mRNA or cDNA and

6                   detecting hybridization between the polynucleotide and the  
7 mRNA or cDNA.

1                   5. The method of claim 4 wherein the polynucleotide comprises  
2 DNA or RNA.

1                   6. The method of claim 4 wherein the polynucleotide comprises  
2 a nucleotide analog selected from the group consisting of phosphorothioates,  
3 phosphoramidates, methyl phosphonates, chiral-methyl phosphonates, 2-O-methyl  
4 ribonucleotides, and peptide-nucleic acids.

1 7. The method of claim 4 wherein the polynucleotide comprises a  
2 detectable moiety, and the step of detecting hybridization comprises detecting the  
3 moiety.

1 8. The method of claim 4 wherein the polynucleotide is a primer  
2 and the step of detecting hybridization comprises:  
3 initiating reverse transcription of prothymosin mRNA with  
4 the primer, and  
5 detecting a prothymosin mRNA reverse transcript;  
6 whereby detection of the reverse transcript indicates that the  
7 polynucleotide has specifically hybridized to prothymosin mRNA.

1 9. The method of claim 4 wherein the prothymosin mRNA or  
2 cDNA is immobilized and the step of contacting comprises contacting the  
3 immobilized mRNA or cDNA with the polynucleotide.

1 10. The method of claim 4 wherein the polynucleotide is  
2 immobilized and the step of contacting comprises contacting the immobilized  
3 polynucleotide with the prothymosin mRNA or cDNA.

1 11. The method of claim 7 wherein the detectable moiety is a  
2 fluorescent label, a radioactive label, an enzymatic label, a biotinyl group, or an  
3 epitope recognized by a secondary reporter.

1 12. The method of claim 9 wherein the biological sample is a  
2 fixed tissue sample and the step of contacting comprises contacting the  
3 polynucleotide with the mRNA or cDNA *in situ* on the fixed tissue sample.

1 ~~13. The method of claim 12 wherein the immobilized~~  
2 ~~polynucleotide is comprised within a polynucleotide array.~~  
3

1 14. The method of claim 3 wherein the step of detecting comprises  
2 the steps of:

3 amplifying the prothymosin mRNA or cDNA to produce an  
4 amplification product and  
5 detecting the amplification product.

1 15. The method of claim 14 wherein the step of detecting the  
2 amplification product comprises:

3 contacting the amplification product with a polynucleotide of  
4 at least 7 to about 50 nucleotides in length that specifically hybridizes to the  
5 amplification product, and

6 detecting hybridization between the polynucleotide and the  
7 amplification product.  
8

1 16. The method of claim 14 wherein the step of detecting the  
2 amplification product comprises determining the nucleotide sequence of the  
3 amplification product.

1 17. The method of claim 14 wherein the step of detecting the  
2 amplification product comprises determining the mass of the amplification product.

1 18. The method of claim 15 wherein the polynucleotide  
2 comprises DNA or RNA.

1 19. The method of claim 15 wherein the polynucleotide  
2 comprises a nucleotide analog selected from the group consisting of  
3 phosphorothioates, phosphoramidates, methyl phosphonates, chiral-methyl  
4 phosphonates, 2-O-methyl ribonucleotides, and peptide-nucleic acids.

1 20. The method of claim 15 wherein the polynucleotide comprises  
2 a detectable moiety, and the step of detecting hybridization comprises detecting the  
3 moiety.

1 21. The method of claim 20 wherein the detectable moiety is a  
2 fluorescent label, a radioactive label, an enzymatic label, a biotinyl group, or an  
3 epitope recognized by a secondary reporter.

1 22. The method of claim 1 wherein the prothymosin gene product  
2 is prothymosin polypeptide.

1 23. The method of claim 22 wherein the step of detecting  
2 comprises detecting prothymosin polypeptide by immunoassay.

1 24. The method of claim 22 wherein the step of detecting  
2 comprises contacting the sample with an affinity agent that binds to prothymosin  
3 polypeptide and detecting binding between the affinity agent and the prothymosin  
4 polypeptide.

1 25. The method of claim 22 wherein the step of detecting  
2 comprises detecting an analyte in the sample having the mass of prothymosin  
3 polypeptide.

1 26. The method of claim 23 wherein the immunoassay is non-  
2 competitive immunoassay.

1 27. The method of claim 23 wherein the immunoassay is  
2 competitive immunoassay.

1 28. The method of claim 23 wherein the immunoassay comprises  
2 detecting binding between the prothymosin polypeptide and an antibody comprising  
3 a detectable moiety selected from the group consisting of a fluorescent label, a  
4 radioactive label, an enzymatic label, a biotinyl group, and an epitope recognized  
5 by a secondary reporter.

1 29. The method of claim 24 wherein the step of detecting binding  
2 comprises detecting bound prothymosin polypeptide by mass spectrometry.

1                   30. The method of claim 26 wherein the non-competitive  
2 immunoassay comprises the steps of:  
3                   capturing the prothymosin polypeptide from the sample on a  
4 solid phase with a first antibody specific for prothymosin polypeptide; and  
5                   detecting capture of the prothymosin polypeptide by  
6 contacting the solid phase with a second antibody specific for prothymosin  
7 polypeptide and detecting binding between the second antibody and prothymosin  
8 polypeptide.

1                   31. The method of claim 26 wherein the non-competitive  
2 immunoassay comprises the steps of:  
3                   binding the prothymosin polypeptide from the sample to a  
4 solid phase; and  
5                   detecting the prothymosin polypeptide by contacting the solid  
6 phase with an antibody specific for prothymosin polypeptide and detecting binding  
7 between the antibody and prothymosin polypeptide.

1                   32. A method for use in the monitoring the progress of  
2 endometriosis in a subject comprising the steps of:  
3                   detecting a first test amount of a prothymosin gene product  
4 in a sample from the subject at a first time;  
5                   detecting a second test amount of the prothymosin gene  
6 product in a sample from the subject at a second, later time; and  
7                   comparing the first test amount with the second test amount,  
8 whereby an increase in the amount between the first time and  
9 the second time indicates progression of endometriosis and a decrease in the  
10 amount between the first time and the second time indicates remission of  
11 endometriosis.

1                   33.     A kit comprising a compound that binds a prothymosin gene  
2 product and instructions to (1) use the compound for detecting prothymosin in a  
3 patient sample, and (2) to diagnose endometriosis based on an elevated amount of  
4 the prothymosin gene product in the sample compared with a normal amount of  
5 prothymosin.

1                   34.     The kit of claim 33 wherein the prothymosin gene product is  
2 prothymosin mRNA or cDNA and the compound is a polynucleotide that  
3 hybridizes with prothymosin mRNA or cDNA under stringent conditions.

1                   35.     The kit of claim 33 wherein the prothymosin gene product is  
2 prothymosin polypeptide and the compound is an antibody that specifically binds to  
3 prothymosin polypeptide.

1                   36.     A method for use in the diagnosis of endometriosis in a subject  
2 comprising detecting a prothymosin gene product in endometriotic tissue from the  
3 subject *in vivo*, whereby detection of the gene product provides a positive  
4 indication in the diagnosis of endometriosis.

1                   37.     The method of claim 36 comprising administering to the  
2 subject a compound that specifically binds to a prothymosin gene product and  
3 detecting binding between the compound and the prothymosin gene product.

1                   38.     The method of claim 37 wherein the compound comprises a  
2 gamma-emitting or positron-emitting radioisotope and binding is detected by  
3 detecting the radioisotope by camera imaging or Geiger counter.

1                   39.     The method of claim 37 wherein the compound comprises a  
2 paramagnetic isotope and binding is detected by detecting the paramagnetic isotope  
3 by magnetic resonance imaging ("MRI").

1                   40.     The method of claim 37 wherein the compound is a  
2 polynucleotide that specifically hybridizes to prothymosin mRNA.

1                   41. The method of claim 37 wherein the compound is an  
2 antibody that specifically hybridizes to prothymosin polypeptide.

1                   42. A method for the treatment of endometriosis in a subject  
2 comprising:  
3                   administering to the subject a probe comprising a detectable  
4 label and a ligand that specifically binds a prothymosin gene product, to allow  
5 binding between the probe and the prothymosin gene product;  
6                   identifying an endometriotic lesion *in situ* by locating bound  
7 label; and  
8                   excising the endometriotic lesion.

1                   43. The method of claim 42 comprising:  
2                   administering the probe into the peritoneum of the subject,  
3 wherein the probe comprises an antibody ligand that specifically binds prothymosin  
4 and a radioactive label;  
5                   identifying an endometriotic lesion *in situ* by locating bound  
6 probe with a Geiger counter; and  
7                   excising the endometriotic lesion laparoscopically.

1                   44. A screening method for determining whether a compound  
2 modulates the expression of a prothymosin gene product in an endometrial cell  
3 comprising the steps of:  
4                   contacting the cell with the compound; and  
5                   determining whether expression of the prothymosin gene  
6 product is different that expression in a control cell which has not been contacted  
7 with the compound;  
8                   whereby a difference between expression in the endometrial  
9 cell and the control cell indicates that the agent modulates expression of the  
10 prothymosin gene product.

1                   45. The method of claim 44 wherein:  
2                   the endometrial cell is comprised within endometriotic tissue  
3 cultured as a xenograft in a mouse;  
4                   the step of contacting comprises administering the compound  
5 to the mouse;  
6                   the step of determining comprises *in vitro* determination of  
7 expression of the gene product after removing the tissue from the mouse.

1                   46. A method for the treatment of endometriosis in a subject  
2 comprising the step of administering to the subject a compound that decreases  
3 prothymosin activity in eutopic endometrial tissue or ectopic endometrial tissue in  
4 the subject.

1                   47. The method of claim 46 wherein the compound inhibits  
2 expression of prothymosin mRNA.

1                   48. The method of claim 46 wherein the compound inhibits  
2 activity of prothymosin protein.

1                   49. The method of claim 46 wherein the compound is a small  
2 organic molecule.

1                   50. The method of claim 46 wherein the compound is  
2 administered intraperitoneally.

1                   51. The method of claim 47 wherein the compound comprises an  
2 inhibitory polynucleotide comprising a sequence of at least 7 nucleotides identical  
3 or complementary to prothymosin mRNA sequence, wherein the inhibitory  
4 polynucleotide inhibits transcription, processing or translation of prothymosin  
5 mRNA.



1                   52.    The method of claim 51 wherein the inhibitory  
2 polynucleotide is a polynucleotide comprising an antisense sequence of at least 7  
3 nucleotides that specifically hybridizes to a nucleotide sequence within  
4 prothymosin mRNA, whereby the polynucleotide inhibits the activity of the  
5 prothymosin mRNA.

1                   53.    The method of claim 51 wherein the inhibitory  
2 polynucleotide is a ribozyme that cleaves prothymosin mRNA.

1                   54.    The method of claim 52 wherein the antisense sequence is  
2 between 10 and 50 nucleotides in length.

1                   55.    The method of claim 52 wherein the polynucleotide  
2 comprises a nucleotide analog selected from phosphorothioates, phosphoramidates,  
3 methyl phosphonates, chiral-methyl phosphonates, 2-O-methyl ribonucleotides and  
4 peptide-nucleic acids.

1                   56.    The method of claim 52 wherein the step of providing the  
2 cells with the polynucleotide comprises transfecting the cells with an expression  
3 vector comprising expression control sequences operatively linked to a nucleotide  
4 sequence encoding the antisense polynucleotide, whereby the vector expresses the  
5 polynucleotide.